DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Amendment to Add a New Method for the Analysis of Sulfites in Foods

Docket No. FDA-2019-N-0463

Final Regulatory Impact Analysis
Final Regulatory Flexibility Analysis
Unfunded Mandates Reform Act Analysis

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Executive Summary

This final rule will amend the regulations that specify the methods of analysis that the Food and Drug Administration (FDA) uses to determine the concentration of sulfites in foods. This rule applies only to FDA. The currently specified method of analysis is the Monier-Williams method as refined by FDA. This is currently known as the optimized Monier-Williams method (OMW method). This rule will replace the reference to the Monier-Williams method and the appendix that refines the methodology with an updated reference to the OMW method. Additionally, this rule will include in the regulations a recently developed, accurate, and more efficient analytical method of analysis, referred to as the Liquid Chromatography Tandem Mass Spectrometry Method (LC-MS/MS method). Upon finalization of this rule, FDA will determine sulfite concentrations in foods primarily using the LC-MS/MS method. We estimate that this rule will produce benefits in the form of cost savings from time saved by using the LC-MS/MS method.[1] Over a ten-year time horizon, the present value of our primary estimates of benefits is $1.1 million using a three percent discount rate and $0. 9 million using a seven percent discount rate. This proposed rule would result in both one-time validation costs and recurring materials costs associated with use of the LC-MS/MS method. Our primary estimate of the present value of costs is $0.19 million using a three percent discount rate and $0.16 million using a seven percent discount rate. The present value of our primary estimates of net benefits is $0.9 million using a three percent discount rate and $0.74 million using a seven percent discount rate.

1 There will be no impact from the update to the incorporation by reference for FDA's current methodology (i.e., the optimized Monier-Williams method) because only the reference will change, not the method.

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I. Introduction and Summary

A. Introduction

We have examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). We believe that this final rule is not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the scope of this rule is limited to FDA, we certify that the final rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $158 million, using the most current (2020) Implicit Price Deflator for the Gross Domestic Product. This final rule will not result in an expenditure in any year that meets or exceeds this amount.

B. Summary of Costs and Benefits

This final rule will amend the regulations that specify the method of analysis FDA uses to determine the concentration of sulfites in foods. Regulations currently specify the Monier-Williams method, incorporated by reference to the "Official Methods of Analysis of the Association of Official Analytical Chemists," 14th Ed. (1984) and modified by 21 CFR part 101 Appendix A. After publication of the current regulation, the Association of Official Analytical Chemists (AOAC) amended the Official Methods of Analysis to include this modified Monier-Williams method, called the "optimized Monier-Williams method" (OMW method). This rule will update the incorporated reference to the OMW method and remove Appendix A. Additionally, this rule will include in the regulations a recently developed, accurate, and more efficient analytical method of analysis, referred to as the LC-MS/MS method. After publication of this final rule, FDA will determine sulfite concentrations in foods primarily using the LC-MS/MS method.

We estimate that this final rule will produce benefits in the form of cost savings from time saved by using the LC-MS/MS method. Over a ten-year time horizon, at a three percent discount rate, the present value of estimated benefits is $1.1 million, with a lower bound of $0.57 million and an upper bound of $1.77 million. At a seven percent discount rate, the present value of estimated benefits is $0.9 million, with a lower bound of $0.47 million and an upper bound of $1.46 million. In Table 1, annualized estimated benefits range from $0.07 million to $0.21 million per year, with a primary estimate of $0.13 million per year, using either a three or seven percent discount rate.

The rule will result in both one-time validation costs and recurring materials costs associated with the LC-MS/MS method. Over a ten-year time horizon, at a three percent

discount rate, the present value of total estimated costs is $0.19 million, with a lower bound of $0.18 million and an upper bound of $0.21 million. At a seven percent discount rate, the present value of total estimated costs is $0.16 million, with a lower bound of $0.15 million and an upper bound of $0.17 million. In Table 1, estimated annualized costs are $0.02 million per year, using either a three or seven percent discount rate.

Net benefits are the difference between benefits and costs. Over a ten-year time horizon, at a three percent discount rate, the present value of estimated net benefits ranges from $0.39 million to $1.57 million, with a primary estimate of $0.90 million. At a seven percent discount rate, the present value of estimated net benefits ranges from $0.32 million to $1.29 million, with a primary estimate of $0.74 million. Using either a three or seven percent discount rate, annualized estimated net benefits range from $0.05 million to $0.18 million per year, with a primary estimate of $0.11 million per year.

Table 1. Summary of Benefits, Costs and Distributional Effects of Final Rule (millions of 2020$)

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
Benefits	Annualized Monetized $millions/year	$0.13	$0.07	$0.21	2020	7%	10 years	Are cost savings
		$0.13	$0.07	$0.21	2020	3%	10 years	Are cost savings
	Annualized Quantified					7%		
						3%		
	Qualitative							
Costs	Annualized Monetized $millions/year	$0.02	$0.02	$0.02	2020	7%	10 years	
		$0.02	$0.02	$0.02	2020	3%	10 years	
	Annualized Quantified					7%		
						3%		
	Qualitative							
Transfers	Federal Annualized Monetized $millions/year					7%		
						3%		
	From/ To	From:			To:			
	Other Annualized					7%		
						3%		

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
	Monetized $millions/year							
	From/To	From:			To:			
Effects	State, Local or Tribal Government: Small Business: Wages: Growth:							

C. Comments on the Preliminary Economic Analysis of Impacts and Our Responses

In 2019, FDA published the proposed rule "Addition of a New Method for the Analysis of Sulfites in Foods." We prepared a comprehensive preliminary regulatory impact analysis for the 2019 proposed rule. Neither of the two comments received on the proposed rule relate to the preliminary economic analysis of impacts.

D. Summary of Changes

The preliminary economic analysis of impacts of the proposed rule used 2017 dollar values. Our final analysis adjusts costs for inflation to 2020 dollar values. Additionally, our final analysis uses updated wage values from the most recent Bureau of Labor Statistics (BLS) Occupational Employment Statistics (May 2020). There are no other substantive changes between this final Regulatory Impact Analysis and the preliminary Regulatory Impact Analysis.

II. Final Economic Analysis of Impacts

A. Background

This final rule will amend the regulations that specify the method of analysis FDA uses to determine the concentration of sulfites in foods. This rule will include the LC-

MS/MS method in the regulations.[2] After publication of this final rule, FDA will determine sulfite concentrations in foods primarily using the LC-MS/MS method. The rule will also replace the existing incorporated reference and corresponding appendix with the AOAC's most recent and comprehensive description of FDA's current practice (i.e., the OMW method).

B. Need for Federal Regulatory Action

Because the Code of Federal Regulations (CFR) explicitly specifies the method of analysis that FDA uses to determine the concentration of sulfites in foods (21 CFR 101.100(a)(4) and 130.9 and 21 CFR part 101 Appendix A), it is necessary to amend the appropriate regulations to allow for the use of the new, accurate, and more efficient method of analysis, the LC-MS/MS method.

C. Purpose of the Rule

This final rule will modernize the regulations that specify the method of analysis FDA uses to determine the concentration of sulfites in foods. The rule will amend the regulation to include the LC-MS/MS method, a new, accurate, and more efficient analytical method. The rule will also update the existing incorporated reference to the AOAC's most recent and comprehensive description of FDA's current practice (i.e., the OMW method).

2 This final rule will not require other entities to use these methods. Other entities will be free to determine the correlation between the official FDA-designated methods and the entity's method of choice for determining sulfite concentrations in foods and to use their scientifically adequate method of choice as they see fit. We do not know of any data sources that would allow us to estimate the distribution of different sulfite-determining methods across entities.

D. Baseline Conditions

The baseline for our analysis is the current state of the world, in which the CFR, which explicitly specifies FDA's current method for determining the concentration of sulfites in foods, does not include the LC-MS/MS method. We define costs and benefits relative to this baseline, which definitionally has zero costs and benefits.

E. Benefits of the Rule

This final rule will produce benefits in the form of cost savings from time saved by using the LC-MS/MS method. There will be no impact from the update to the incorporation by reference for FDA's current methodology (i.e., the OMW method) because only the reference will change, not the method.

We estimate that FDA conducts about 774 analyses per year of sulfite concentrations in foods. Relative to the OMW method, we estimate the LC-MS/MS method will save roughly 2 hours of labor per analysis for a total time savings of roughly 1,548 hours per year. According to the Bureau of Labor Statistics (BLS) Occupational Employment Statistics, the hourly wage of a chemist (occupation code 19-2031) ranges from $21.62 per hour at the 10th percentile to $67.14 per hour at the 90th percentile with a mean estimate of $41.54 per hour (May 2020 figures).[3] Doubling these hourly wages to account for benefits and overhead, we estimate that the total cost of a chemist's time ranges from $43.24 per hour to $134.28 per hour with a mean estimate of $83.08 per hour. Hence, we estimate that the annual cost savings associated with this final rule ranges from $66,936 to $207,865 per year, with a primary estimate of $128,608 per year.

3 U.S. Bureau of Labor Statistics. (2020, May). Occupational and Employment Statistics, May 2020: 19-2031 Chemists. Retrieved from Occupational Employment Statistics: https://www.bls.gov/oes/current/oes192031.htm

In Table 2, over a ten-year time horizon, at a three percent discount rate, the present value of estimated benefits associated with this final rule ranges from $0.57 million to $1.77 million, with a primary estimate of $1.1 million. At a seven percent discount rate, the present value of estimated benefits ranges from $0.47 million to $1.46 million, with a primary estimate of $0.9 million. With either a three or seven percent discount rate, annualized estimated benefits range from $0.07 million to $0.21 million, with a primary estimate of $0.13 million per year.

Table 2. Summary of the Benefits of this Final Rule (millions of 2020$)

	Low	Mean	High
Present Value			
3%	$0.57	$1.1	$1.77
7%	$0.47	$0.9	$1.46
Annualized Amount			
3%	$0.07	$0.13	$0.21
7%	$0.07	$0.13	$0.21

Notes: Present values and annualized values calculated over a ten-year time horizon (t =1 through t = 10).

F. Costs of the Rule

This final rule will result in both one-time validation costs and recurring materials costs associated with use of the LC-MS/MS method. There will be no impact from the update to the incorporation by reference for FDA's current methodology (i.e., the OMW method) because only the reference will change, not the method.

One-Time Validation Costs

We estimate that 3 FDA laboratories spend about 80 hours each on the validation process for the LC-MS/MS method, for a total of 240 hours. Again using BLS Occupational Employment Statistics, the hourly wage of a chemist (occupation code 19-2031) ranges from $21.62 per hour at the 10th percentile to $67.14 per hour at the 90th

percentile with a mean estimate of $41.54 per hour (May 2020 figures). Doubling these hourly wages to account for benefits and overhead, we estimate that the total cost of a chemist's time ranges from $43.24 per hour to $134.28 per hour with a mean estimate of $83.08 per hour. Hence, our estimate of the one-time validation costs associated with this final rule ranges from $10,378 to $32,227, with a primary estimate of $19,939.[4]

Annual Materials Costs

As stated above, we estimate that FDA conducts about 774 analyses per year of sulfite concentrations in foods. Relative to the OMW method, we estimate the LC-MS/MS method will involve materials costs of approximately $26 per analysis. Hence, we estimate that the final rule will result in annual materials costs of roughly $20,400.

Total Costs

In Table 3, over a ten-year time horizon, at a three percent discount rate, the present value of total estimated costs ranges from $0.18 million to $0.21 million, with a primary estimate of $0.19 million. At a seven percent discount rate, the present value of total estimated costs ranges from $0.15 million to $0.17 million, with a primary estimate of $0.16 million. With either a three percent or seven percent discount rate, annualized estimated costs are $0.02 million per year.

Table 3. Summary of the Costs of this Final Rule (millions of 2020$)

	Low	Mean	High
Present Value			
3%	$0.18	$0.19	$0.21
7%	$0.15	$0.16	$0.17
Annualized Amount			
3%	$0.02	$0.02	$0.02

4 We do not estimate validation costs associated with the current OMW method because these are incurred regardless of analysis scenario. Let X = LC-MS/MS method validation costs and Y = OMW method validation costs. Under the baseline, total validation costs equal Y. Under the final rule, total validation costs equal Y + X. As stated in Section II(D) of this regulatory impact analysis, we estimate final rule costs relative to the baseline. Hence, the validation costs associated with the final rule equal Y + X – Y = X.

7%	$0.02	$0.02	$0.02

Notes: Present values and annualized values calculated over a ten-year time horizon (t =1 through t = 10).

G. Net Benefits of the Final Rule

Net benefits, shown in Table 4, are the difference between benefits and costs. Over a ten-year time horizon, at a three percent discount rate, the present value of estimated net benefits ranges from $0.39 million to $1.57 million, with a primary estimate of $0.9 million. At a seven percent discount rate, the present value of estimated net benefits ranges from $0.32 million to $1.29 million, with a primary estimate of $0.74 million. Using either a three or seven percent discount rate, annualized estimated net benefits range from $0.05 million to $0.18 million per year, with a primary estimate of $0.11 million per year.

Table 4. Summary of the Net Benefits of this Final Rule (millions of 2020$)

	Low	**Mean**	**High**
Present Value			
3%	$0.39	$0.90	$1.57
7%	$0.32	$0.74	$1.29
Annualized Amount			
3%	$0.05	$0.11	$0.18
7%	$0.05	$0.11	$0.18

Notes: Present values and annualized values calculated over a 10 year time horizon (t =1 through t = 10).

H. Distributional Effects

As the scope of this final rule will be limited to FDA, we do not expect this rule to have any distributional effects.

I. International Effects

As the scope of this final rule will be limited to FDA, we do not expect this rule to have any international effects.

J. Uncertainty and Sensitivity Analysis

The greatest source of uncertainty in this analysis is our estimate of the time savings from using the LC-MS/MS method versus the current method. We test our model's sensitivity to this uncertainty using a breakeven analysis. Namely, we estimate the amount of time that must be saved for benefits to equal costs (i.e., to "break even"). At a three percent discount rate, the time savings necessary to break even ranges from 182 to 497 hours per year, with a primary estimate of 273 hours per year. At a seven percent discount rate, the breakeven time savings ranges from 187 to 501 hours per year, with a primary estimate of 278 hours per year. Our breakeven analysis in Table 5 shows that achieving even just one-third of our main time savings estimate of 1,548 hours per year would still result in positive net benefits.

Table 5. Breakeven Analysis of the Annual Time Savings of this Proposed Rule

	Low	**Mean**	**High**
Breakeven Time Saved Per Year			
3%	179 *(12%)*	273 *(18%)*	499 *(32%)*
7%	184 *(12%)*	278 *(18%)*	504 *(32%)*

Notes: Breakeven time savings as a percentage of original time savings estimate of 1,548 hours per year given in parentheses.

K. Analysis of Regulatory Alternatives to the Rule

The only feasible regulatory alternative to the final rule is the baseline.

III. Final Small Entity Analysis

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this rule is limited in scope to FDA and will not require other entities to use the methods of analysis FDA uses to determine the concentration of sulfites in foods, we certify that the

final rule will not have a significant economic impact on a substantial number of small entities. This analysis, as well as other sections in this document, serves as the Final Regulatory Flexibility Analysis, as required under the Regulatory Flexibility Act.